K113043

DEC 2 0 2011

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SUMMIT MEDICAL PRODUCTS

510(k) Summary

Device Sponsor:	Summit Medical Products, Inc. 2480 South Main Street Suite 212 Salt Lake city, UT 84115
Registration Number:	1722214
Trade Names:	Direct Antibiotic Infusion Kit
Common Name:	Catheter Introducer Kit
Classification Name:	Catheter Introducer Kit
Product Code:	LJS
Regulation Number:	880.5970
Equivalent To:	None
Device Description:	The Direct Antibiotic Infusion kit product line is a convenience kit for doctors. The Direct Antibiotic Infusion kit is designed to allow a physician or heath care provider to have the devices needed to administer antibiotics. The Direct Antibiotic Infusion kit consists of the following components: 1. Short or long term in-dwelling Catheter. 2. Suture. 3. Tubing anchor. 4. Tegaderm dressing. 5. Providone Iodine 10% ointment
Indications for Use:	The Direct Antibiotic Infusion Kit is intended for direct administration of mediation and/or fluids into the body. The Direct Antibiotic Infusion kit is intended for use by a physician or by a trained individual under the supervision of a physician. Any drug(s) used with this kit is (are) at the discretion of the physician and the indications for the drug should be verified and followed.
Substantial Equivalence (SE) Rational:	There is no substantial equivalence for the Direct Antibiotic Infusion kit.
Standards:	Standards are listed with the individual device 510K clearance
Contact Information:	Marko Van Amen Summit Medical Products, Inc VP of Regulatory Affairs/Quality Assurance 2480 South Main Street Suite 212. Salt Lake City, UT 84115 Phone: 801-352-1888. FAX: 801-352-1818
Date Submitted	December 13, 2011

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 0 2011

Summit Medical Products, Inc.
% Mr. Marko Van Amen
VP of Regulatory Affairs and Quality Assurance
2480 S. Main Street, Suite 212
Salt Lake City, Utah 84115

Re: K113043
Trade/Device Name: Direct Antibiotic Infusion Kit
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: Class II
Product Code: LJS, GAT, FRO, JCY
Dated: October 06, 2011
Received: October 13, 2011

Dear Mr. Van Amen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market the device, subject to the general controls provisions of Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In

addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kit contains Povidone Iodine 10% Ointment which is subject to regulation as a drug.

Our substantially equivalent determination does not apply to the drug component of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug component. For information on applicable Agency requirements for marketing this drug, we suggest you contact:

Director, Division of Drug Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SUMMIT MEDICAL PRODUCTS

Traditional 510(k) – Direct Antibiotic Infusion kit

510(k) Number :

Device Name: Direct Antibiotic Infusion Kit

Indications for Use:

The Direct Antibiotic Infusion Kit is intended for direct administration of mediation and/or fluids into the body. The Direct Antibiotic Infusion kit is intended for use by a physician or by a trained individual under the supervision of a physician. Any drug(s) used with this kit is (are) at the discretion of the physician and the indications for the drug should be verified and followed.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113043